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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,698	07/03/2003	Bhiku G. Patel	03-40102-US	7194

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William J. McNichol, Jr., Esquire
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,698

Applicant(s)

PATEL ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/30/03</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 09/30/2003; and petition to make special, filed 4/19/2005. The petition was granted on 05/09/2005.

Claims 1-20 are included in the prosecution.

Specification

1. The use of the trademarks "Lucidol", "Carbopol", "Versene", Puramex ZN", "Glycopure", "Finsolve TN", "Arlacel", "Brij", "Tween", and "Steareth" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the

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following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-18, the expressions "low enough", "substantially uniformly absorb", "substantially retained" and "substantially uniformly delivered" do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions. Clarification is requested.

5. Claims 19 and 20 contain the trademark/trade name "steareth". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App.

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1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe surfactants and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6, 7, 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,562,642 ('642).

US '642 discloses a non-woven pad impregnated by dermatologically active ingredients wherein the non-woven material is capable of absorbing a flowable liquid composition of the active ingredients (abstract; col.4, lines 37-39; col.5, lines 25-31; col.8, lines 21-34). The active ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic (col.10, lines 46-52). The composition is an emulsion and has low viscosity (col.12, lines 46-50; col.14, lines 38-40). The composition further comprises carbomer, and C₁₂-C₁₅ alkyl benzoate (col.13, line 33; col.14, lines 60-65). The pad is contained in a container comprising aluminum foil layer in contact or sealed

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with thermoplastic layer that is sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad can be impregnated by antifungal agent or other dermatologically active agents (col.11, lines 50-52).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4, 5, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '642

The teachings of US '642 are discussed above. US '642 does not teach the claimed particle size and viscosity.

The claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests the low viscosity of the liquid composition as implied by the flowability of the composition in order to be absorbed into the non-woven pad.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain flowability of the composition suitable for the composition to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,183,766 ('766) in view of US '642 and further in view of US 6,861,397 ('397) and US 5,821,237 ('237).

US '766 teaches non-woven pad impregnated by composition in the form of emulsion comprising: starch (col.7, line 33; col.10, line 46; col.16, lines 33-37); benzoyl peroxide (col.12, line 56); carbomer in amount of 0.01-10% (col.10, line 66; col.11, lines

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8-35); water (col.18, example 1); glycerin (col.11, line 42); zinc lactate in amount of 0.1-10% (col.10, line 25); dimethicone in amount of 0.01-5% (col.4, line 41); and mixture of surfactants selected from glyceryl stearate and PEG 100 stearate, steareth 2, steareth 20, and polysorbate (col.14, lines 15-22).

US '766 does not teach the container. The reference also does not teach C₁₂-C₁₅ alkyl benzoate which is well known in the cosmetic art.

US '642 teaches pad contained in a container comprising aluminum foil layer in contact or sealed with thermoplastic sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad is a non-woven pad impregnated with active ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic (col.10, lines 46-52). The composition has low viscosity (col.12, lines 46-50; col.14, lines 38-40). The composition further comprises carbomer, and C₁₂-C₁₅ alkyl benzoate (col.13, line 33; col.14, lines 60-65).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pad impregnated with all the desired ingredients including C₁₂-C₁₅ alkyl benzoate as disclosed by US '766 and to package the pad in the container disclosed by US '642, motivated by the teaching of US '766 that this packaging is not prone to premature rupture but provides ready dispensing of the package contents with reasonable expectation of having a non-woven pad impregnated with the desired effective liquid that is packaged in a container that is not prone to premature rupture but provides ready dispensing of the package contents.

US '766 in combination with US '642 do not teach sodium hydroxide, cetearyl alcohol, or EDTA, which are all known ingredients in the cosmetic art.

US '397 teaches topical composition that is highly effective in short time period and effectively deposits a topically active agent to provide residual benefit on the skin (abstract; col.5, lines 62-67). The composition comprises EDTA, sodium hydroxide and cetearyl alcohol (col.16, lines 36-45; col.61, appendix C).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide non-woven pad in a container wherein the pad is impregnated by the desired composition as disclosed by the combined teachings of US '766 and US '642 and add sodium hydroxide EDTA and cetearyl alcohol to the composition as taught by US '397, motivated by the teachings of US '397 that composition comprising those agent is highly effective in short time period and effectively deposits a topically active agent to provide residual benefit on the skin, with reasonable expectation of having pad in container that is highly effective in short time and deposits active agents when applied to the skin.

The combination of US '766, US '642 and US '397 does not teach the glycolic acid in the composition, which is known ingredient in the cosmetic art.

US '237 teaches topical composition impregnated into non-woven pad, the composition comprises EDTA to enhance the effect of the preservatives. The composition also comprises glycolic acid to improve the texture of the skin (col.16, lines 20-29; col.21, lines 60-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide non-woven pad in a container wherein the pad is impregnated by the desired composition as disclosed by the combined teachings of US '766, US '642 and US '397 and add glycolic acid and EDTA to the composition as taught by US '237, motivated by the teaching of US '237 that glycolic acid improves the texture of the skin and EDTA enhances the effect of preservatives, with reasonable expectation of having a pad in container that improves the skin texture when wiped to the skin, and well preserved at storage.

Allowable Subject Matter

12. Claim 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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Isis Ghali

